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The contribution and histopathological correlation of MRI in BI-RADS category 4 solid lesions detected by ultrasonography

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Ethics Committee Approval
Approval for the study was obtained from the 'Non-invasive Clinical Research Ethics Committee' of Aydın Adnan Menderes University (No: 2018/1333), on February 22, 2018.
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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Abstract

Background/Aim: BI-RADS category 4 breast lesions have widely varying malignancy rates and they are almost always evaluated with biopsy. However, especially in the 4a subgroup with a benign character of up to 98%, many patients undergo unnecessary invasive procedures. Breast MRI can be a good problem-solving method to reduce unnecessary invasive procedures, but there are very few publications on BI-RADS category 4 solid lesions. This study aimed to investigate the contribution of breast MRI in Breast Imaging Reporting and Data System (BI-RADS) category 4 solid mass lesions detected by Mammography and Ultrasonography.

Methods: In this retrospective cohort study, ultrasound reports of patients examined in the radiology breast imaging unit between January 2015 and December 2017 were reviewed. Cases reported as BI-RADS category 4 with a solid mass on ultrasonography were determined. Patients without histopathological diagnosis and/or breast MRI were excluded from the study. After the implementation of the exclusion criteria, 121 solid lesions of 104 female patients were included in the study. US and MRI images of the patients were re-evaluated by two radiologists and BI-RADS scoring was performed again. The obtained data were analyzed statistically together with histopathological data.

Results: With breast MRI, 74 of 121 BI-RADS category 4 lesions were downgraded while 13 lesions were upgraded. Of the 74 downgraded lesions, 61 were BI-RADS category 2 and 3, which do not require a biopsy. Only one of these lesions was histopathologically malignant. Of the 13 lesions upgraded, 6 were in BI-RADS category 5, two of which were benign. The sensitivity, specificity, positive and negative predictive values of MRI were 93.8%, 56.2%, 24.6%, and 98.3%, respectively.

Conclusion: In our study, breast MRI reduced the BI-RADS categories to 2 and 3 in approximately half of the BI-RADS category 4 solid lesions detected by ultrasound. Therefore, problem-solving MRI may be useful to avoid unnecessary invasive procedures in these patients.

Keywords: BI-RADS category 4, Breast ultrasonography, Breast MRI, Breast cancer, Solid breast lesions

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Introduction

Breast Ultrasonography (US) is a widely used imaging modality to evaluate breast abnormalities of young women, and in those with dense breast tissue due to low sensitivity of mammography (MG). Due to high dependence on the operator, the sensitivity and specificity of US vary between the studies. Previous studies reported 81-98% sensitivity, 33-89% specificity, 13-68% positive predictive value (PPV), and 92-100% negative predictive value (NPV) for US Breast Imaging and Data System (BI-RADS) classification [1].

Breast magnetic resonance imaging (MRI) is the most sensitive method to detect breast cancer (90-95%), although it has relatively low specificity (37-72%) when compared with MG and US [2,3]. There are recent studies that report that the specificity of breast MRI has increased in parallel with the developing technology [4, 5]. Although it has a high false-positive predictive value, negative breast MRI safely excludes malignancy with a high negative predictivity (91.7-100%) [4, 6]. Therefore, especially in selected cases, breast MRI use is increasing day by day in addition to conventional breast assessment methods for diagnostic and problem-solving purposes [7, 8]. Although MRI falls into the American College of Radiology (ACR) BI-RADS classifications published in 2003, the MRI guidelines for BI-RADS category 4 lesions are not fully specified [9].

The malignancy risks of BI-RADS category 4 breast lesions vary widely (2-95%) and they are evaluated in 3 subgroups. BI-RADS category 4a has low (2-10%), 4b has moderate (10-50%) and 4c has high (50-95%) malignancy possibility [10]. Although the probability of benignity reaches 98% especially in the BI-RADS category 4a, these lesions are considered to require pathological correlation rather than problem-solving MRI due to the risk of malignancy [10,11]. However, we think that breast MRI may reduce the need for biopsy due to its high sensitivity and negative predictive value.

This study aimed to investigate the contribution of breast MRI and its predictivity in reducing invasive biopsy procedures in BI-RADS category 4 solid mass lesions detected by MG and US.

Materials and methods

Approval for the study was obtained from the 'Non-invasive Clinical Research Ethics Committee of our institution (No: 2018/1333) on February 22, 2018.

Patient selection

A total of 2143 patients who underwent breast US in our clinic between January 2015 and December 2017 were scanned retrospectively. Images of 353 patients with BI-RADS category 4 in their radiological report were re-evaluated. Patients whose biopsy results were unavailable and who did not have MRIs were excluded from the study. A total of 121 lesions of 104 cases which were found to have solid mass showing suspicious malignant characteristics (BI-RADS category 4) were included in the study.

Mammography and tomosynthesis imaging

MG was performed in Mammomat Inspiration (Siemens, Erlangen, Germany), with standard craniocaudal (CC) and mediolateral oblique (MLO) views and additional views (lateral, spot compression, etc.) when necessary.

Tomosynthesis was performed in the MLO position with the tube moving at an arch angle of 25°. The resulting projection images were reconstructed with a cross-sectional thickness of 1 mm. MG and tomosynthesis images were evaluated on an MG-specific Workstation (MammoReport, Siemens, Erlangen, Germany).

MG examination was performed in all patients over 45 years of age and/or patients with a high risk of malignancy. All MG images were evaluated by or under the supervision of a 13-year-experienced radiologist.

Ultrasound imaging

All US examinations were performed on Acuson Antares (Siemens, Erlangen, Germany) ultrasound device. Sonograms were obtained with a 6-13 MHz wide band matrix transducer on breast preset. Patients under 45 years of age and without additional malignancy risk were evaluated by US alone. Patients over the age of 45 years and/or high risk of malignancy were first evaluated with MG, then US. All US examinations were performed by or under the supervision of a 13-year-experienced radiologist.

Magnetic resonance imaging

All breast MRIs of the patients were performed in a 1.5 T MRI device (Achieva, Philips MS, Eindhoven, The Netherlands), with a dedicated 7-channel nozzle coil, in the prone position. Breast MRI parameters were as follows: First, axial T1W spin-echo sequence (TR / TE: 454 / 10ms, FOV: 300, Matrix: 432, section thickness 3mm); next, axial T2W short tau invasion recovery (STIR: TR (TE: 2000/173 msec, FOV: 300, Matrix: 432, 2 mm section thickness) images were obtained. In the dynamic examination, axial 3D T1W gradient-echo sequence (THRIVE: TR / TE: 7 / 3.4 msec, matrix: 352, FOV: 340, flip angle 10º, 1 mm section thickness) was repeated 6 times in precontrast and postcontrast. Gadolinium contrast agent 0.1 mM/kg (Gadoteratmeglumine, Dotarem®, Guerbet, France; Gadobutrol, Gadovist®, Bayer Healthcare, Germany; Gadodiamide, Omniscan®, GE Healthcare, USA) was administered intravenously at 2 ml/sec with an automatic injector (Medrad Spectris Solaris EP, Bayer Radiology Solutions, Whippany, NJ, USA) and washed with 10 ml saline. MR images were evaluated on a mammography-specific Workstation (MammoReport, Siemens, Erlangen, Germany).

Image evaluation

The images of the patients who were diagnosed as BI-RADS category 4 in MG and US were re-evaluated by two radiologists with 13 years of experience in breast imaging by examining US, MG, and MRI findings with a common consensus.

All cases were re-classified with US and MG images using the fifth edition of the ACR BI-RADS Atlas [11,12]. The masses with partially circumscribed margins, complex cystic and solid lesions were noted as category 4a, masses with indistinct margins and/or amorphous or fine pleomorphic calcifications were considered category 4b, and masses with new indistinct margins and/or fine linear calcifications were recorded as category 4c. Masses with spiculated or irregular margins,

architectural distortion, skin/nipple retractions, and/or fine linear or linear branching calcifications were considered category 5.

Breast MRIs of all patients were also re-evaluated by a radiologist with 13 years of breast radiology experience, and the lesions were divided into three groups as focus, mass, and non-mass enhancement. In a mass lesion, irregular shape, microlobulated contour, and indistinct margin were considered suspicious and noted as BI-RADS category 4. An oval or round-shaped mass with a smooth margin was considered benign. Lesions with high T1 and T2 signals were considered benign, and low or medium T2 signals were considered suspicious. Homogeneous, heterogeneous, and circular enhancement patterns were considered suspicious in mass lesions. Enhancement of the internal septa was interpreted as a marker of malignancy (BI-RADS category 5), and internal septal structures without enhancement were interpreted in favor of benignity (BI-RADS category 3). In addition to the enhancement patterns, contrast kinetic curves of all mass lesions were obtained. Lesions with persistent (type 1) kinetic curves were considered benign, while lesions showing plateau (type 2) or wash-out (type 3) were suspicious for malignancy. In the non-mass enhancement group, the distribution and shape of the lesion were evaluated. Ductal, linear, segmental, and regional non-mass enhancements were considered suspicious. Considering the morphology of the lesions, T1 and T2 signal characteristics, enhancement patterns and kinetics, and associated findings (adenopathy, skin/nipple retractions or invasions, etc.) all lesions were re-classified according to the fifth edition of ACR BI-RADS Atlas [13].

Histopathological examination

All lesions of patients were histopathologically evaluated. In some patients, histopathological sampling was obtained by imaging-guided percutaneous tru-cut biopsy method, and in others, by surgical excision. Percutaneous biopsy was performed with US-guided 14G cutting needle biopsy with an automatic gun (Magnum, Bard biopsy systems, Tempe, USA). The obtained specimens were evaluated by a single pathologist working specifically on breast pathology.

Statistical analysis

A total of 121 lesions of 104 patients were included in the study. Re-evaluated MG, US, and MRI findings and BI-RADS scores, histopathological diagnosis of the lesions, and demographic data of the patients were recorded as numbers and percentages. SPSS version 22.0 was used for statistical analysis. Kolmogorov Smirnov test was used for normality analysis. Pearson's and Spearman correlation tests were utilized in normally and non-normally distributed data, respectively. Histopathological diagnosis was considered the gold standard diagnostic method. Accordingly, sensitivity, specificity, negative and positive predictive values, and accuracy rates of the examinations were calculated.

Results

A total of 121 lesions of 104 patients were examined. The mean age of the patients was 50.60 ± 8.83 (27-71) years. Sixty-two (59.6%) patients were in the premenopausal period. Ten (9.6%) of the patients had a risk factor.

According to MG and US BI-RADS, 70 (57.9%) were BI-RADS category 4a, 22 (18.2%) were BI-RADS category 4b and 29 (24.0%) were BI-RADS category 4c. MRI findings of these lesions are shown in Table 1.

Of the 121 BI-RADS category 4 solid lesions identified in US, 13 (10.7%) were upgraded, and 74 (61.2%) were downgraded after MRI. Of the 6 lesions upgraded to MRI BI-RADS category 5, one was category 4a and 5 were category 4c. Seven lesions were upgraded with MRI between category 4 subgroups, of these, 3 were upgraded from 4a to 4b, and 4, from 4a to 4c. With MRI, 17 of 74 lesions were downgraded to category 2, 44 lesions were downgraded to category 3, which did not require biopsy. Thirteen lesions were downgraded among category 4 subgroups and did not cause any change in clinical approach. MRI BI-RADS distribution according to BI-RADS category 4 subtypes is shown in Table 2.

Table 1: Distribution of lesions with MRI findings according to BIRADS subtypes

MRI findings	MG + US BI-RADS Categories		
	Category 4a (n=70)	Category 4b (n=22)	Category 4c (n=27)
Mass (n=95)	59 (84.3%)	15 (68.2%)	21 (72.4%)
Non-mass enhancement (n=8)	3 (4.3%)	2 (9.1%)	3 (10.3%)
Focus (n=18)	8 (11.4%)	5 (22.7%)	5 (17.3%)

MG: mammography, US; ultrasonography, MRI: magnetic resonance imaging, BI-RADS: breast imaging reporting and data system

Table 2: MRI BI-RADS classification of lesions according to MRI findings

MRI BI-RADS	MG + US BI-RADS Categories		
	Category 4a (n=70)	Category 4b (n=22)	Category 4c (n=29)
Category 1 (n=0)	---	---	---
Category 2 (n=17)	12 (17.1%)*	4 (18.2%)*	1 (3.5%)*
Category 3 (n=44)	30 (42.8%)*	9 (40.9%)*	5 (17.2%)*
Category 4a (n=32)	20 (28.6%)	3 (13.6%)*	9 (31.0%)*
Category 4b (n=10)	3 (4.3%)	6 (27.3%)	1 (3.5%)*
Category 4c (n=12)	4 (5.7%)	---	8 (27.6%)
Category 5 (n=6)	1 (1.5%)	---	5 (17.2%)

MG: mammography, US; ultrasonography, MRI: magnetic resonance imaging, BI-RADS: breast imaging reporting and data system

Seven of 13 upgraded lesions with MRI and three of 74 downgraded lesions were histopathologically diagnosed as malignant. Only one of these 3 lesions was downgraded into the group that did not require biopsy (BI-RADS category 3) (false-negative rate 1/74 = 1.3%) Histopathological classification of cases that had been upgraded or downgraded by MRI according to BI-RADS category 4 subtypes is shown in Tables 3.

Table 3: Histopathological results of MRI-upgraded and MRI-downgraded cases

MG + US BI-RADS Categories	Benign lesions							Malign lesions			
	FA	SA	IDP	Atypic IDP	ADH	FCD	other	IDC	DCIS	other	Total
MRI upgraded lesions											
Category 4a	2	1	1	0	0	0	1	2	1	0	8
Category 4b	0	0	0	0	0	0	0	0	0	0	0
Category 4c	0	1	0	0	0	0	0	3	0	1	5
Total	2	2	1	0	0	0	1	5	1	1	13
MRI downgraded lesions											
Category 4a	13	6	2	2	4	4	10	1	0	0	42
Category 4b	8	2	0	1	0	0	5	0	0	0	16
Category 4c	5	2	0	0	0	0	7	2	0	0	16
Total	26	10	2	3	4	4	22	3	0	0	74

MG: mammography, US: ultrasonography, BI-RADS: breast imaging reporting and data system, MRI: magnetic resonance imaging, FA: fibroadenoma, SA: sclerosing adenosis, IDP: intraductal papilloma, ADH: atypic ductal hyperplasia, FCD: fibrocystic disease, IDC: intraductal carcinoma, DCIS: ductal carcinoma in-sutu

Histopathological findings

According to the histopathological examination of 121 lesions' specimens obtained through US-guided core needle biopsies, 107 (88.4%) were benign and 14 (11.6%) were malignant. The distribution of histopathological examinations according to BI-RADS subtypes is shown in Table 4.

Due to clinical-pathological incompatibility, surgical excision was performed in 30 of 107 lesions which were diagnosed as benign in the core needle biopsy. Twenty-eight

(93.3%) of these lesions were diagnosed as benign and 2 (6.7%) were diagnosed as malignant.

Table 4: Histopathological distribution according to BIRADS subtypes

Pathological diagnosis	MG + US BI-RADS Category			MRI BI-RADS Category						
	4a	4b	4c	1	2	3	4a	4b	4c	5
Benign										
FA (n=35)	20	9	6	0	6	19	6	3	1	0
SA (n=20)	11	5	4	0	4	4	6	4	1	1
IDP (n=3)	3	0	0	0	0	2	0	0	1	0
A. IDP (n=4)	2	1	1	0	1	2	0	0	1	0
ADH (n=5)	5	0	0	0	0	4	1	0	0	0
FCD (n=4)	3	1	0	0	1	2	0	1	0	0
others (n=34)	20	6	8	0	5	10	15	2	1	1
Malign										
DCIS (n=1)	1	0	0	0	0	0	0	0	1	0
IDC (n=13)	5	0	8	0	0	1	4	0	5	3
others (n=2)	0	0	2	0	0	0	0	0	1	1
Total (n=121)	70	22	29	0	17	44	32	10	12	6

MG: mammography, US: ultrasonography, BI-RADS: breast imaging reporting and data system, MRI: magnetic resonance imaging, FA: fibroadenoma, SA: sclerosing adenosis, IDP: intraductal papilloma, ADH: atypic ductal hyperplasia, FCD: fibrocystic disease, DCIS: ductal carcinoma in-sutu, IDC: intraductal carcinoma

In total, 39 of 121 lesions underwent surgical excision. Sixteen of 18 (88.9%) lesions in BI-RADS category 4a were diagnosed as benign and 2 (11.1%) were malignant; all 4 lesions in BI-RADS category 4b were diagnosed as benign, and 8 of 17 (47.1%) lesions in BI-RADS category 4c were diagnosed as benign and 9 (52.9%) were diagnosed as malignant.

Sixty-four (91.4%) of the 70 lesions in BI-RADS category 4a were diagnosed as benign, 6 (8.6%) were diagnosed as malignant. All 22 lesions (65.5%) in BI-RADS category 4b and 29 BI-RADS category 4c lesions were diagnosed as benign, while ten (34.5%) BI-RADS 4c lesions were diagnosed as malignant.

In our study, the sensitivity, specificity, PPV, and NPV of MRI were 93.8%, 56.2%, 24.6%, and 98.3%, respectively. Two patient samples whose BI-RADS category was upgraded and downgraded as a result of the MRI examination were given in Figure 1 and Figure 2, respectively.

Figure 1: A 51-year-old female patient who had an operation history due to right breast invasive ductal carcinoma. a: A smooth solid lesion with minimal size increase was detected in the left upper outer quadrant in the follow-up ultrasonography (US), b: No vascularization was found in Doppler US, and considered as BI-RADS category 4a, c: On T2 weighted MRI images, the lesion was hyperintense, d: On Diffusion Weighted Images the lesion was hyperintense, e: The lesion was enhanced in postcontrast series, f: The time-contrast curve chart of the irregular margined lesion shows a plateau enhancement (type 2 pattern). (f: vertical axis indicates the percentage of enhancement, and the horizontal axis indicates the time in seconds). Due to irregular margins and enhancement pattern, the BI-RADS category of the lesion was upgraded to 5. Micropapillary type invasive ductal carcinoma was diagnosed with biopsy.

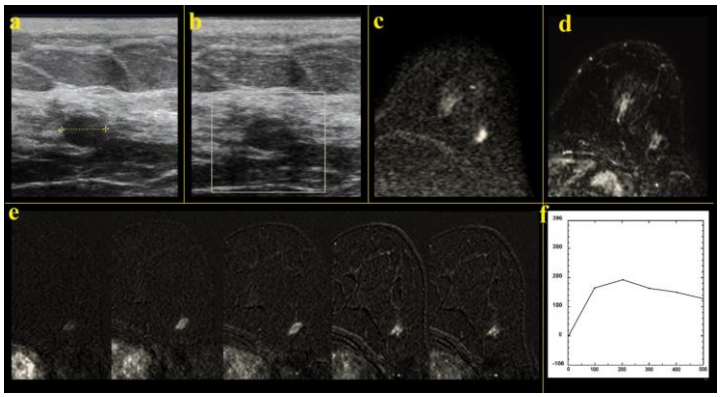
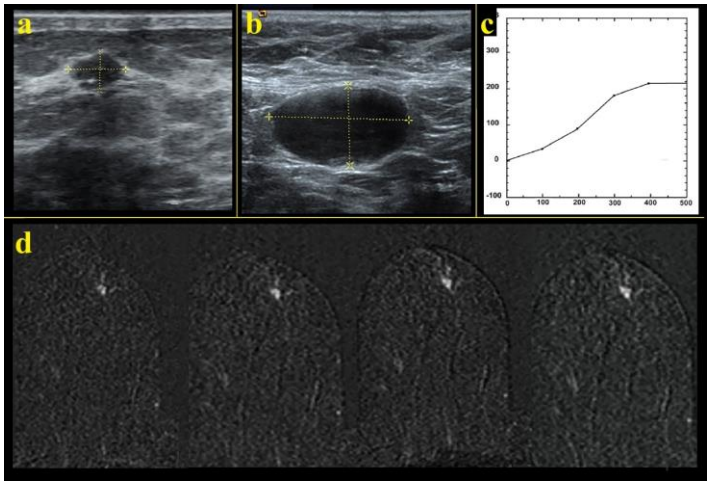


Figure 2: A 61-year-old female patient; an asymmetrically increased density in the retroareolar area of the right breast was found in routine follow-up mammography (MG). The patient was evaluated by ultrasonography (US), a: A solid lobulated contoured solid mass (BI-RADS category 4b) was detected in this region, b: In the ipsilateral axilla, a suspected lymphadenomegaly (LAM) was found, c: The lesion has a persistent enhancement (type 1 pattern) on time-contrast curve chart, d: Dynamic contrast T1W images showed the persistent enhancement of the lesion. Although the T2 hyperintensity and enhancement pattern indicate benignity, the lesion was accepted as BIRADS 4a due to the presence of axillary LAM. Biopsy was performed for suspicion of malignancy, and the lesion was reported as benign ductal hyperplasia and the axillary lymph node was reported as reactive lymphoid hyperplasia.



Discussion

In the present study, we determined that MRI provides a more accurate classification of BI-RADS category 4 solid lesions detected in US, and we think it can be used as a problem solver in the evaluation of these lesions. We found that MRI is more useful in detecting possible malignant findings and referring to biopsy when compared with MG and US. Therefore, problem-solving MRI may contribute to the prevention of unnecessary biopsies, especially for BI-RADS category 4a lesions, which are mostly benign.

BI-RADS category 4 lesions represent a wide range of imaging findings including solid mass with 2-95% malignancy risk, asymmetry, architectural distortion, and calcifications. With the addition of MRI images, mass or non-mass enhancement is also considered within this range. Because of the risk of malignancy, a generally accepted approach is to evaluate these lesions by biopsy [10, 11]. However, since the risk of malignancy is very low, especially in BI-RADS category 4a lesions, new approaches such as problem-solving MRI are needed to reduce the indication for invasive biopsy. In our study, we found that 74 of 121 (61%) breast masses in BI-RADS 4 as categorized by MG and US were downgraded by problem-solving breast MRI and 61 of the 74 downgraded lesions were classified as stage 2 or 3. In terms of BI-RADS category 4a, in 42 (60%) of 70 solid lesions, BI-RADS categories were downgraded to 2 and 3, which did not require biopsy. On histopathological examinations, three lesions were reported as malign in the downgraded group, and only one of them (1.6%) was in the benign spectrum (BI-RADS category 3) on MRI. The malignancy rate was 53.9% (7/13 lesions) in upgraded cases. These findings show that MRI determines the need for biopsy with greater accuracy and significantly contributes to MG and US.

Although studies with problem-solving MRI in breast imaging report some reservations, especially false-positive diagnoses, they are increasing day by day. However, the number

of studies on BI-RADS category 4 lesions is quite low. In our literature review, we did not find any studies conducted on solid lesions only. In almost all studies with BI-RADS category 4 lesions, MRI has a prominent advantage in the recognition of malignant-benign features [14-19]. In most of these studies, false negativity rates of MRI were almost 0% and this finding is very promising in terms of MRI evaluation reducing unnecessary invasive procedures. In the present study, only one patient had false-negative lesions with MRI and our negative predictive value was very high (98.4%), close to the literature. Strobel et al. [18] evaluated 353 BI-RADS category 4 lesions in 340 women with problem-solving MRI and concluded that MRI detected lesions better and reduced the need for biopsy. They found 100% negative predictive value in all cases except microcalcification clusters, without distinguishing solid lesions, and reported that diagnostic MRI could be an alternative assessment tool to biopsy. On the other hand, Giess et al. [19] reported that US has an important contribution in defining the lesion in patients with suspicious mammography findings. However, they stated that radiologists needed problem-solving MRI in 12% of cases despite US. They predicted that, in these cases, breast MRI differentiated malignancy with high sensitivity and negative predictive values and that the problem-solving MRI could reduce the need for biopsy.

The main concern for problem-solving MRI was that breast MRI was in the process of development and the lack of standardization in interpretation. However, in parallel with technological advances, the experience gained in the differentiation of benign-malignant lesions on breast MRI and specialization in this field indicate that it can be used to reduce biopsy indications [9, 17-19]. Another concern is that although MRI is useful in solving certain problems, false positivity values are high. In a study they conducted, Strobel et al. [18] reported that the rate of false positivity was 2.3% and they had benign but high-risk lesions (such as atypical ductal hyperplasia). While the PPV was 73% in the study of Strobel et al., it was reported as 31.9% in the study of Giess et al. [19]. In our study, false positivity rates remained at 24.6%, lower than the literature. This result may be due to interpretative differences, study design (especially lesion selection), high physician-patient anxiety, or local differences.

Limitations

Due to the retrospective planning of the study, there may be differences in the evaluation of images and lesion management among radiologists. The obtained sample may not have represented the real population completely since some lesions were not included in the study because biopsy or operation was performed without MRI due to different opinions and because some lesions were monitored only with US. Another limitation is that the predictions of breast MRI on all solid lesions cannot be determined due to the absence of BI-RADS category 3 and 5 solid lesions in the study. However, since BI-RADS category 3 and 5 lesions do not generally present a problem in BI-RADS classification, and because biopsy is recommended although a great majority of BI-RADS category 4 lesions are benign, these lesions were used in our study to prevent unnecessary biopsies.

Conclusion

In this study, breast MRI reduced the BI-RADS categories to 2 and 3 in approximately half of the BI-RADS category 4 solid lesions detected by ultrasound. Therefore, we think that problem-solving MRI may be useful to avoid unnecessary invasive procedures in these patients.

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